REMARKS

Claims 25, 27-43, 45, 47 and 48 are pending.

Amendments to the Claims

The amendments to claims 25 and 45 are supported, *inter alia*, by the specification at paragraphs 3, 4 and 11 of the published specification. The claims are amended to speed up prosecution and without prejudice or disclaimer of the original subject matter claimed therein. No new matter is added by way of these amendments. The applicants reserve the right to pursue any cancelled subject matter in at a later time.

Claim Objections

The applicants respectfully submit that the objection to claim 38 is moot in view of the amendment of this claim and request that the objection be withdrawn.

Rejections under 35 U.S.C. §112

Claims 25, 27-43, 45 and 47 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the enablement requirement. The applicants disagree but have amended claims 25 and 45 to speed up prosecution and without prejudice or disclaimer of the original subject matter claimed therein. The applicants respectfully submit that the rejection to these claims is moot in view of the amendment and request that the rejection be withdrawn.

Claims 25, 27-43, 45, 47 and 48 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. The office action alleges that the specification do not provide support the limitation "free of a carrier of the oil soluble drug." The applicants

respectfully disagree but have amended independent claims 25 and 47 to recite that the "oil phase is free of a carrier agent used to dissolve the oil-soluble drug." The applicants submit that such carrier agents are taught in paragraph 3 of the published specification. The applicants respectfully submit that the rejection to these claims is moot in view of the amendment and request that the rejection be withdrawn.

Rejections under 35 U.S.C. §103(a)

Claims 25, 27-30, 34, 37-38, 40-41, 43 and 47 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. 6024978 ("Hauer") as evidenced by The Merck Index (1989). Applicants respectfully disagree but have nevertheless amended the claims to speed up prosecution.

When responding to the applicants' arguments submitted in the response of July 7, 2009, the office action states that the claims recite open claim language and do not exclude Transcutol from being present in the hydrophilic phase. Applicants respectfully submit that this argument is moot in view of the amendments to the claims.

The office action cites Example 5.2 of Hauer as disclosing a thickened "emulsion pre-concentrate" comprising cyclosporin, Pluronic F68 and sodium laurylsulphate. The applicants maintain their position that Hauer does not teach or suggest microemulsion pre-concentrates that do not include a carrier, such as Transcutol. Furthermore, because Hauer teaches that such a carrier is present to obtain sufficient cyclosporine loading, Hauer would not give those skilled in the art any reason to prepare a microemulsion that does not include such a carrier.

Hauer teaches a microemulsion pre-concentrate including a hydrophilic phase, a lipophilic phase and a surfactant (column 6, lines 30-50.) Transcutol is taught as being a component of the hydrophilic phase (column 7, lines 14-50), which acts as a carrier for cyclosporine in the hydrophilic phase and

enables cyclosporin loading of the composition that is adequate for convenient therapeutic dosaging (column 8, lines 9-16.)

In view of the amendments and arguments presented above, the applicants respectfully request that the rejection of claims 25, 27-30, 34, 37-38, 40-41, 43 and 47 under 35 U.S.C § 103(a) be withdrawn.

Claims 31-33, 39 and 45 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Hauer in view of WO 9408610 ("Constantinides".) Applicants have discussed Hauer above and respectfully submit that Constantinides does not make up for the deficiencies of Hauer. As such, the cited combination does not teach every element of the claimed compositions. Constantinides teaches emulsions including an oil and a water soluble biologically active agent (page 5, lines 9-17.) Constantinides does not teach or suggest an emulsion having an oil phase including an oil-soluble drug in the absence of separate carrier of the drug.

Furthermore, the applicants respectfully submit that the office action does not set forth a common sense reason to combine the teachings of Hauer and Constantinidies. Constantinidies teaches a composition including an oil, a mixture of high and low HLB surfactants, an aqueous phase and a biologically active agent. However, Constantinidies teaches that the term "biologically active material" refers to materials that are soluble in the hydrophilic phase (see Constantinidies at page 10, lines 28-35.)

Hauer teaches compositions including the biologically active agent cyclosporine. The applicants submit that cyclosporin is at the most sparingly soluble in water and therefore is not equivalent to the biologically active materials referred to by Constantinidies. At the time of the invention, one skilled in the art would have had no reason to combine the teachings of Hauer with the teachings of Constantinidies. Applicants respectfully request that the rejection of claims 31-33, 39 and 45 under 35 U.S.C § 103(a) be withdrawn.

Claims 35-36 and 42 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Hauer as evidenced by The Merck Index (1989, page 1364) in view of The Merck Index (1989, page 478).

Applicants have discussed Hauer above and respectfully submit that they have addressed the deficiencies of this reference. Applicants respectfully request that the rejection of claims 34-36, 39 and 42 under 35 U.S.C § 103(a) be withdrawn.

Claims 25, 27-41, 43, 45 and 47-48 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Glen (U.S. Patent Number 4798846) in view of Constantinides. The office action cites Glen as teaching pharmaceutical compositions including 2, 6-diisopropylphenol either alone or dissolved in a water-immiscible solvent emulsified with water by means of a surfactant. Constantinides is cited as teaching microemulsions comprising an oil and a mixture of high and low HLB surfactants. According to the office action, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Glen and Constantinidies and utilize sodium laurate in combination with another HLB surfactant such as Tween 80 or Pluronic F68.

The applicants respectfully disagree and submit that the office action does not set forth a common sense reason to combine the teachings of Glen and Constantinidies. Constantinidies teaches a composition including an oil, a mixture of high and low HLB surfactants, an aqueous phase and a biologically active agent. However, Constantinidies teaches that the term "biologically active material" refers to materials that are soluble in the hydrophilic phase (see Constantinidies at page 10, lines 28-35.)

Glenn teaches compositions including the biologically active agent 2, 6-diisopropylphenol (propofol.) The applicants submit that propofol is at most sparingly soluble in water and therefore is different from the biologically active

materials referred to by Constantinidies. At the time of the invention, one skilled in the art would have had no reason to combine the teachings of Glen, directed to compositions including a sparingly water soluble biologically active agent, with the teachings of Constantinidies. Applicants respectfully request that the rejection of claims 25, 27-41, 43, 45 and 47-48 under 35 U.S.C § 103(a) be withdrawn.

Applicants submit that the claims are now in condition for allowance. If, for any reason, the Examiner is unable to allow the application and wishes to resolve any remaining issues, the undersigned attorney may be contacted at (312) 321-4229.

Respectfully submitted,

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